Serial Number: 10/027,800

Filing Date: December 20, 2001

itle: CARDIAC RHYTHM MANAGEMENT SYSTEM WITH ARRHYTHMIA CLASSIFICATION AND ELECTRODE SELECTION

Page 8 Dkt: 279.372US1

SYSTEM

REMARKS

This responds to the Office Action mailed on September 10, 2004. Claims 1, 9, 18, 21, and 30 are amended. No claims are canceled or added. As a result, claims 1-32 remain pending in this application.

§102 Rejection of the Claims

Claims 1-15, 17-27, 29, 30 and 32 were rejected under 35 U.S.C. § 102(e) for anticipation by Lu (U.S. Patent No. 6,654,639). Applicant respectfully traverses.

As an initial note, Applicant does not admit that Lu is prior art and reserves the right to swear behind it at a later date as provided under 37 C.F.R. § 1.131. Nevertheless, Applicant believes that these claims are distinct over Lu for the reasons stated below.

Concerning claims 1-15, 17-27, and 29:

Applicant can find no disclosure, teaching, or suggestion in the cited portions of Lu of classifying the detected arrhythmia into an arrhythmia classification that specifies at least a sequence in which a heart contraction depolarization is received by at least three of the electrodes during the arrhythmia, as presently recited or incorporated in these claims. In responding to the Applicant's previous remarks, the present Office Action states:

Lu states in col. 11, lines 15-23 that the origin of the arrhythmia can be determined in the presence of the arrhythmia by determining any differences in cardiac interval durations and/or changes in the activation sequence.

(Office Action at 4.) Thus, the Office Action apparently takes the position that determining the origin of the arrhythmia constitutes classification of the arrhythmia. With this response, Applicant has amended these claims to overcome this basis of rejection. More particularly, these claims presently recite or incorporate classifying the detected arrhythmia into an arrhythmia classification that specifies at least a sequence in which a heart contraction depolarization is received by at least three of the electrodes during the arrhythmia. Applicant respectfully submits that Lu's classification into an origin of the arrhythmia does not constitute a classification that actually specifies a sequence in which a heart contraction depolarization is received by at least

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Title: CARDIAC RHYTHM MANAGEMENT SYSTEM WITH ARRHYTHMIA CLASSIFICATION AND ELECTRODE SELECTION

SYSTEM

three of the electrodes. Instead, Lu apparently abstracts depolarization sequence information into a classification that merely specifies the origin of the arrhythmia:

Page 9 Dkt: 279.372US1

When one or more of the cardiac cycle intervals is less than the predefined tach_threshold value, thus signifying the presence of tachycardia, the origin of the tachycardia can be determined by observing any differences in the cardiac interval duration and/or changes in the cardiac signal activation sequence, e.g., if the left atrial cardiac signal 142 precedes the right atrial cardiac signal 140, the origin of the tachycardia is typically the left atrium.

(Lu at col. 11, lines 15 - 22.) As is seen from this passage from Lu, the origin of the arrhythmia is apparently determined by which electrode first detects the cardiac activation. However, any such apparent arrhythmia "classification" according to the origin of the arrhythmia fails to specify the sequence in which a heart contraction depolarization is received by at least three of the electrodes during the arrhythmia. For example, once Lu's arrhythmia has been classified as left atrial in origin (as an illustrative example), that arrhythmia classification as to origin would apparently not include information specifying whether the cardiac activation that was first detected by a left atrial electrode was then detected first by a right ventricular electrode or a left ventricular electrode. By contrast, the present claims recite an arrhythmia classification that specifies such an exact sequence of depolarization reception by at least three electrodes, so that anti-arrhythmia therapy can be appropriately tailored for different activation sequences. This is explained in the present patent specification by Table 1 and page 8, lines 16 – 18. Because Lu merely "classifies" an arrhythmia during the arrhythmia according to its origin, it fails to disclose, teach, or suggest such capability. Accordingly, because Lu does not disclose, teach, or suggest all claim elements, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

Concerning claims 9, 30, and 32:

Claim 9 presently recites classifying the detected arrhythmia into an arrhythmia classification that specifies at least the sequence in which the heart contraction depolarization is received at the electrodes, and a value of a difference between the times at which the heart contraction depolarization is received by at least two of the electrodes. Claims 30 and 32 presently recites or incorporates an arrhythmia classification that actually specifies at least both:

(1) a sequence in which a heart contraction depolarization is received at the electrodes during the

Serial Number: 10/027,800

Filing Date: December 20, 2001

Title: CARDIAC RHYTHM MANAGEMENT SYSTEM WITH ARRHYTHMIA CLASSIFICATION AND ELECTRODE SELECTION

Page 10 Dkt: 279.372US1

SYSTEM

detected arrhythmia, and (2) a time difference value between reception of the heart contraction depolarization at sequentially adjacent pairs of electrodes during the detected arrhythmia.

By contrast, Lu apparently merely classifies the arrhythmia according to its origin, as discussed above. Applicant cannot find any disclosure, teaching, or suggestion in Lu of, among other things, an arrhythmia classification that actually specifies a time difference value between reception of the heart contraction depolarization at a pair of electrodes during the detected arrhythmia. Accordingly, because Lu does not disclose, teach, or suggest all claim elements, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

§103 Rejection of the Claims

Claims 16, 28 and 31 were rejected under 35 USC § 103(a) as being unpatentable over Lu (U.S. Patent No. 6,654,639) in view of Adams (U.S. Patent No. 5,425,749). Applicant respectfully traverses on two grounds.

First, Applicant notes that dependent claims 16, 28, and 31 incorporate all of the language of their independent claims 1, 18, and 30, respectively. However, for the reasons explained above, Applicant cannot find all elements of such claims in Lu and/or Adams. Accordingly, Applicant respectfully submits that no *prima facie* case of obviousness presently exists with respect to claims 16, 28, and 31.

Second, Applicant notes that the Office Action states:

Adams therefore suggests that a measure of rate instability (i.e., rate variability) may be employed in order to discriminate between fibrillation and other more stable non-fibrillation events (col. 1, lines 39-45). The determination of rate stability/variability is an old and well-known method for detecting fibrillation. Any artisan of ordinary skill in the cardiac therapy art desiring to enhance patient safety by allowing for quick application of defibrillating energy, would have seen the obviousness of providing the device of Lu with the capability to determine rate variability given the teachings of Adams and the general knowledge available in the cardiac treatment arts.

(Office Action at 4.) However, even if one were to assume that Adams teaches rate variability, the present claims recite something altogether different—a variability in the classification. As discussed above, the present claims use an arrhythmia classification that specify the sequence at which depolarizations are received at various electrodes. Such sequence can vary even if rate

Serial Number: 10/027,800

Filing Date: December 20, 2001

Title:

CARDIAC RHYTHM MANAGEMENT SYSTEM WITH ARRHYTHMIA CLASSIFICATION AND ELECTRODE SELECTION

Page 11 Dkt: 279.372US1

does not. Therefore, Applicant respectfully submits that variability in the present arrhythmia classification is distinguishable from the rate variability of Adams.

In view of the above, Applicant respectfully submits that no prima facie case of obviousness presently exists with respect to claims 16, 28, and 31. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

Page 12 Dkt: 279.372US1

Serial Number: 10/027,800

Filing Date: December 20, 2001

Title:

CARDIAC RHYTHM MANAGEMENT SYSTEM WITH ARRHYTHMIA CLASSIFICATION AND ELECTRODE SELECTION

SYSTEM

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 373-6951 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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November 2,2004

Reg. No. 42,267

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop RCE, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this ______ day of November, 2004.

Name

Signature